REVISION

MAR 30 2000

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0005
CUSTOMER NUMBER: 436

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

U S Army Chppm
Medical/Toxicology Division
5158 Blackhawk Rd. Mchb
Aberdeen Prov Grnd, MD 21010

Telephone: (b)(6), (b)(7)c

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessarv or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					130
7. Hamsters					0
8. Rabbits		14		4	18
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					
House Mouse(wild)			4		4
Deer Mouse spp.		24	184		208
Chipmunk		19			19

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) *The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.*

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

NED
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(AUG 91)

Fncl

FY2005 APHIS Form 7023 Column E Explanation – Part II (USDA Report Correction FEB 2006)

1. Registration Number: 51-F-0005 / 436

2. Species (common name) of animals used in the study: Rabbits

3. Number of animals used in this study (in this pain category): 2

4. Explain the procedure producing pain and/or distress.

Instilled 0.1 ml test article (TiO2 HFE-7200 + 15% peracetic acid) into right eye. One animal developed diffuse conjunctival redness, with swelling of the nictitans and minor ocular discharge within one hour. Signs did not progress. All signs except nictitans swelling resolved by Day 7. Nictitans swelling resolved by Day 14. The other animal developed conjunctival redness, swelling and minor ocular discharge within 1 hour, then developed a pinpoint corneal opacity/ulceration within 24 hours, which had resolved by 72 hrs post-administration.

The modification describing this procedure did predict up to 50% Category E animals. However, this was still unexpected on a practical level, with regards to potential pain category, as other studies with this compound had shown only very mild/minor reactions.
The classification of these animals as Column E is extremely conservative, as neither animal ever exhibited signs of pain or distress such as changes in weight, changes in feed or water consumption, changes in feces or urine output, hunching, hyperresponsiveness, aggression, depression, or related signs.

Topical medications were not administered, per the protocol, due to possible interference with grading. However, as stated previously, both animals continued to appear bright, alert, and responsive, with no changes in eating or drinking habits and normal feces and urine output, and no other signs of pain or distress, throughout the time period in question. As such, systemic medications were not administered (as per the protocol).

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

a. The EPA Health Effects Test Guidelines (Primary Eye Irritation) state that a mammalian species shall be used and that the rabbit is the preferred species. The albino rabbit is the recommended species due to its size and the extensive historical database.

b. The nature of the studies precludes the use of totally painless procedures. An attempt to alleviate pain or distress by the administration of topical analgesics or anesthetics may alter the manifestation of the ocular response and subsequent grading. The observation of the onset, duration and/or reversibility of ocular signs is critical to interpretation of results. Toxic signs are defined in TOX SOP 63, Test System Evaluation. Animals that experience pain or distress significant enough to warrant systemic analgesics would be entirely removed from study based on protocol and SOP criteria.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The EPA Health Effects Test Guidelines (Primary Eye Irritation) state that a mammalian species shall be used and that the rabbit is the preferred species. The albino rabbit is the recommended species due to its size and the extensive historical database that exists.

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